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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/460,715 06/02/95 MACH

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HM12/1105  
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EXAMINER

WORTMAN, D

ART UNIT

PAPER NUMBER

1648

27

DATE MAILED:

11/05/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/460,715

Applicant(s)

MACH ET AL.

Examiner

Donna C. Wortman, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 24 August 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 7,8 and 19-39 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 7,8 and 19-39 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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Claims 21, 35-37 and 39 were amended and claim 40 was cancelled in Paper No. 24. Claims 7 and 8 remain withdrawn from consideration as drawn to a non-elected invention. Claims 19-39 are under examination.

The following is a quotation of the first paragraph of 35 U.S.C.

112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record in rejecting claims 21 and 24-40 in the previous Office action. All the pending claims are now included in this rejection because Applicant's remarks in Paper No. 24 indicate that no claims are intended to be limited to strain Ad169.

Applicant has argued that one of skill in the art would be able to locate restriction fragments in other strains of HCMV that encode pp28 despite the fact that the pp28 encoding sequence occurs on entirely different HindIII and other restriction fragments than the fragments of Ad169; that it is possible to screen an HCMV strain library with a cDNA clone and localize the relevant sequence to a(n) HCMV restriction fragment; and that Pande confirms that it was well within the skill of one of ordinary skill in the art to isolate the restriction fragments.

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Applicant's arguments have been considered but not found persuasive. It is apparent that the specification does not provide any guidance for identifying the particular pp28-encoding restriction fragments in any HCMV strains except for Ad169, and Pande et al. provides evidence that HindIII and other restriction fragments differ from one HCMV strain to another. Pande et al., upon which Applicant apparently wishes to rely for guidance as to how to locate the appropriate DNA, is a post-filing date reference. The sufficiency of the disclosure under 35 USC 112, first paragraph, is judged as of its filing date (In re Glass, 492 F.2d 1228, 1232, 181 USPQ 31, 34 (CCPA 1974)). Further, Applicant may not rely upon supporting documents to supply that which the disclosure lacks.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19, 21, 24-36, 38, and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is indefinite in reciting "said DNA molecule does not comprise an entire HindIII R fragment from the genome of human cytomegalovirus strain Ad169" because it is not clear what the intended DNA does comprise and what the claim encompasses.

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Claim 25-36 are indefinite in reciting fragments of fragments that include a sequence, etc. The metes and bounds of these claims remain unclear for reasons of record.

With respect to claim 19, Applicants state that they intend to claim a DNA molecule encoding HCMV pp28, or antigenic portions thereof that elicit antibodies that immunologically bind to pp28, but not an entire HindIII R fragment from HCMV strain Ad169, and also all DNA molecules that encode HCMV pp28, or antigenic portions thereof that elicit antibodies that immunologically bind to pp28 from all HCMV strains, and that the claim does cover HindIII R fragment from strain Ad169, minus one base pair.

With respect to claims 25-36, Applicants state that they intend the claims to cover HindIII R from HCMV strain Ad169, minus one base pair, but not an entire HindIII R fragment from HCMV.

Applicants remarks have been considered but not found sufficient to clarify the metes and bounds of claims 19 and 25-36; if anything, the claim language is even more confusing than before since it is not clear what is being claimed in terms of either Ad169 or "all HCMV strains." Further, the metes and bounds of "a fragment of a fragment" remain as unclear as ever; the limitations of the claimed DNA molecule cannot be unambiguously determined.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19, 21, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Ihara et al., of record, interpreted in light of Pande et al. (Virology 184:762-767, 1991, not prior art) of record.

Ihara et al. disclose cleavage maps of the genome of HCMV Towne strains for HindIII, Bam H I, Eco R I, and Xba I (Fig. 4) and also the results of recleavage of Hind III fragments with other restriction endonucleases (Table 1). Pande, Fig. 1, shows the relationship between the Hind III restriction maps of HCMV Towne and AD169; it is apparent that DNA corresponding to HindIII R fragment of AD169 is contained within the HindIII B fragment of the Towne strain. The disclosure of Ihara, Fig. 4, is deemed to anticipate the claimed subject matter because the restriction fragment DNA molecules inherently contain sequences encoding pp28 or parts thereof and do not contain the HindIII R fragment of AD169 since they do not originate from AD169. The disclosure of Ihara, Table 1, the Hind III fragment B, and the Bam H I, Eco R I, and Xba I recleavage fragments of fragment B, inherently contain sequences encoding pp28 or parts thereof and do not contain the HindIII R fragment of AD169 since they do not originate from AD169.

A rejection over prior art is now made because of Applicants' remarks in response to the previous rejection under 35 USC 112, second paragraph, and the resulting broader interpretation of claims 19, 21, and 25. Consequently, the action is made final.

This application contains claims 7 and 8 drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final

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rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Wortman whose telephone number is (703) 308-1032. The examiner can normally be reached on Monday through Thursday from 7:30 am to 5:00 pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Donna Wortman, Art Unit 1648, and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1648 FAX telephone number for official papers is (703) 308-4242. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday, or Federal Holiday with the

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District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

A handwritten signature in black ink, appearing to read 'D. Wortman', with a long horizontal stroke extending to the right.

Donna C. Wortman, Ph.D.  
Primary Examiner

November 2, 2001